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(54) **MECHANICAL EMBOLECTOMY DEVICE AND METHOD**

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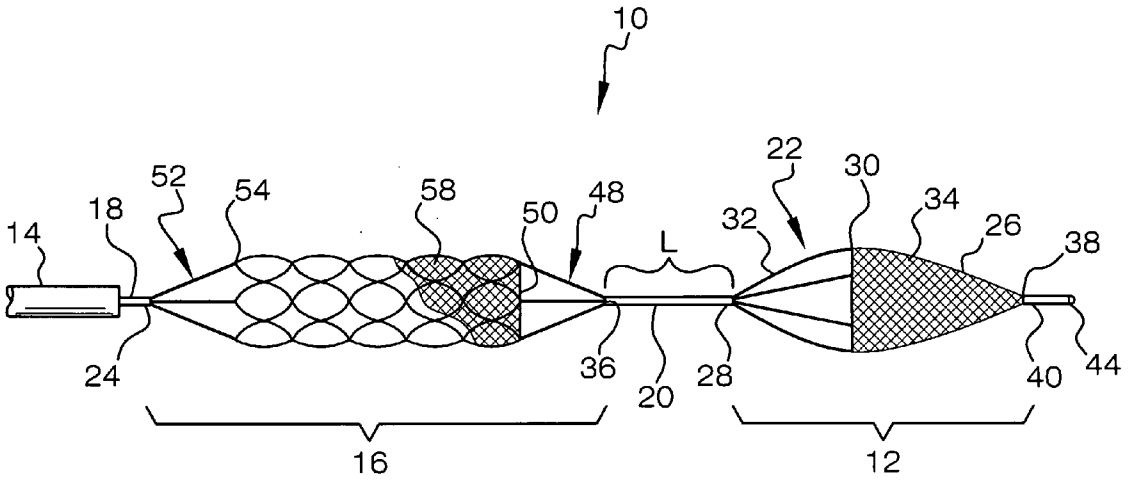
(57) **ABSTRACT**

An embolectomy device includes an elongated shaft positionable in and movable within a catheter. The elongated shaft having a distal end portion. An expander portion having proximal and distal ends. The expander portion having a first plurality of legs connecting the proximal end of the expander portion to the distal end portion of the elongated shaft and a second plurality of legs connecting the distal end of the expander portion to the proximal end of the intermediate elongated shaft. The expander portion being biased to expand laterally outward from the long axis of the embolectomy device when the expander portion has been moved out of the catheter to engage a clot. A retrieval portion can be provided proximally of the expander portion. A retrieval net can be fixed to the retrieval portion. The expander portion can be at least partially covered by a net. A method for removing clots and other occlusions for body canals is also provided.



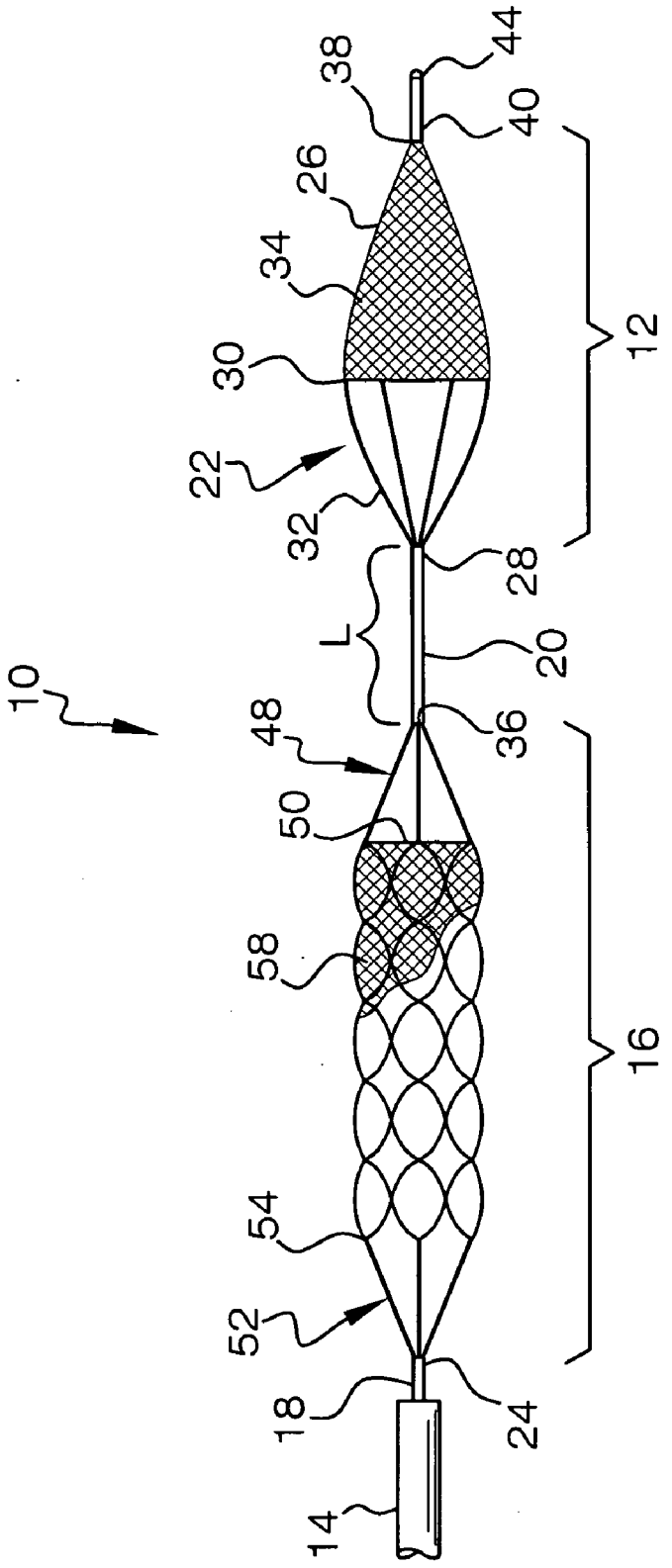


FIG. 1

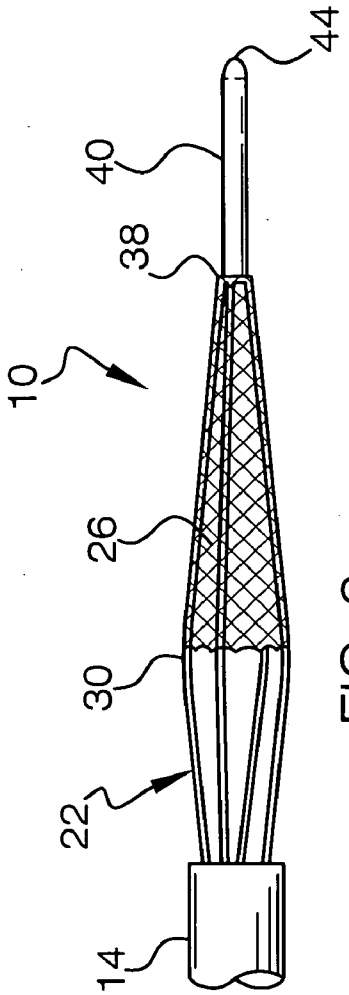


FIG. 2

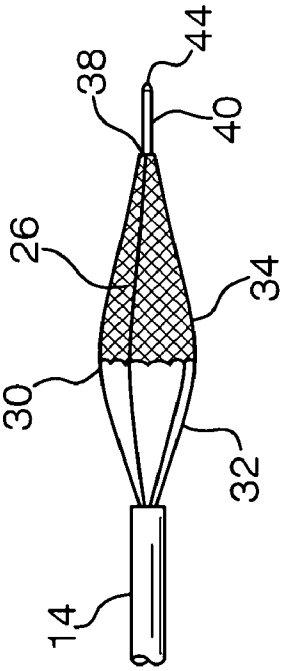


FIG. 3

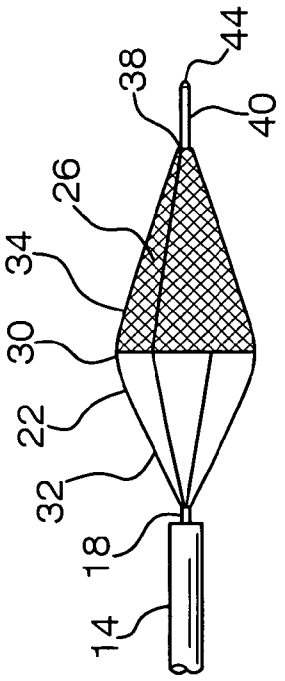


FIG. 4

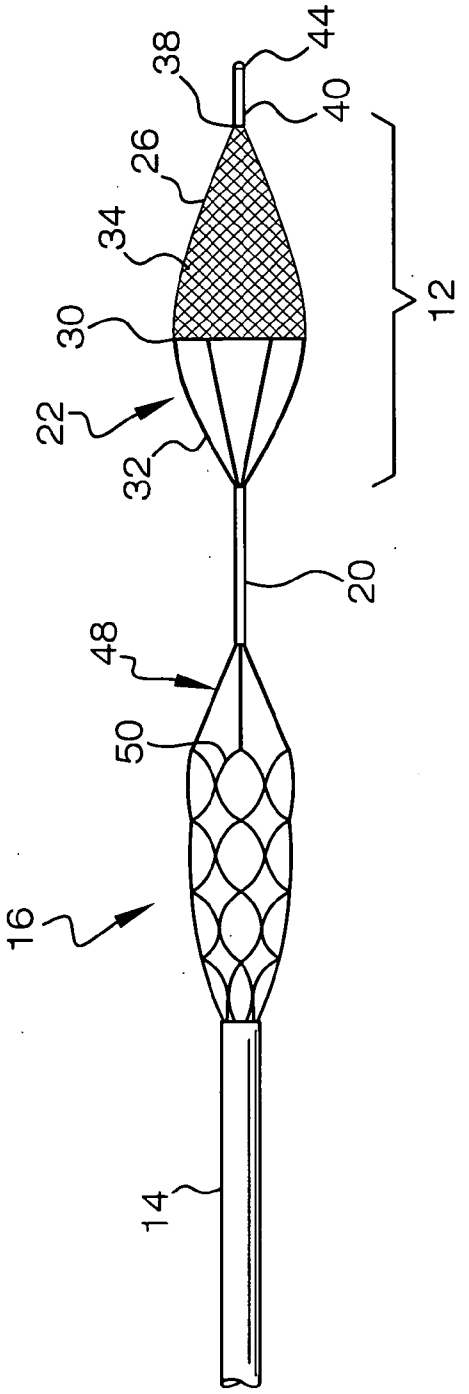


FIG. 5

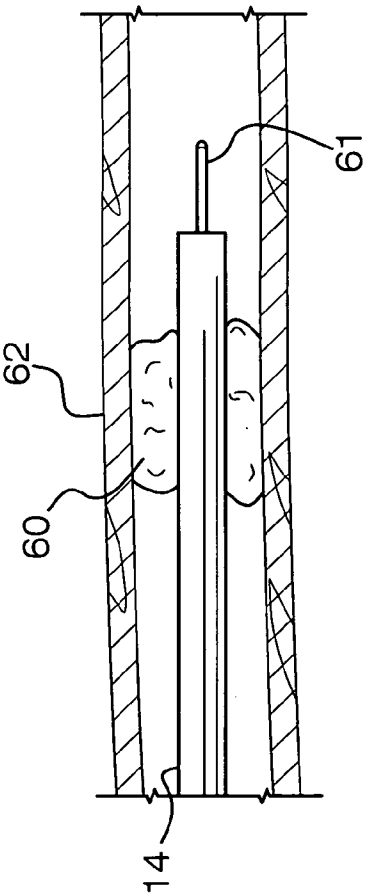


FIG. 6

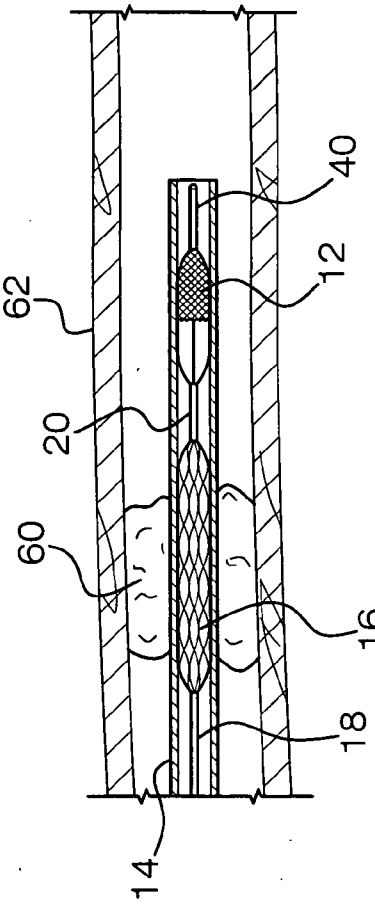


FIG. 7

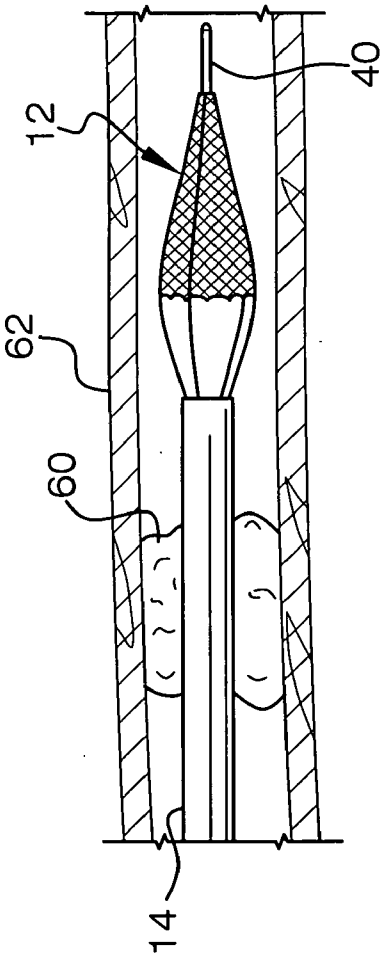


FIG. 8

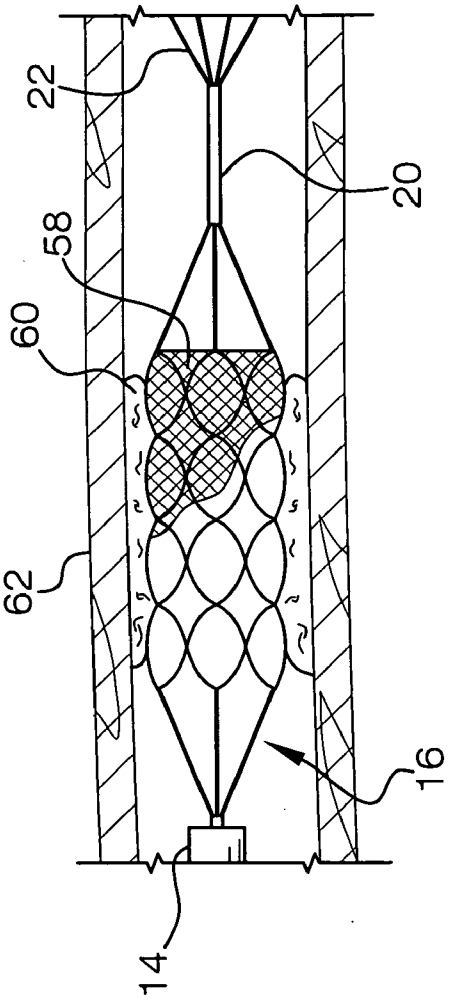


FIG. 9

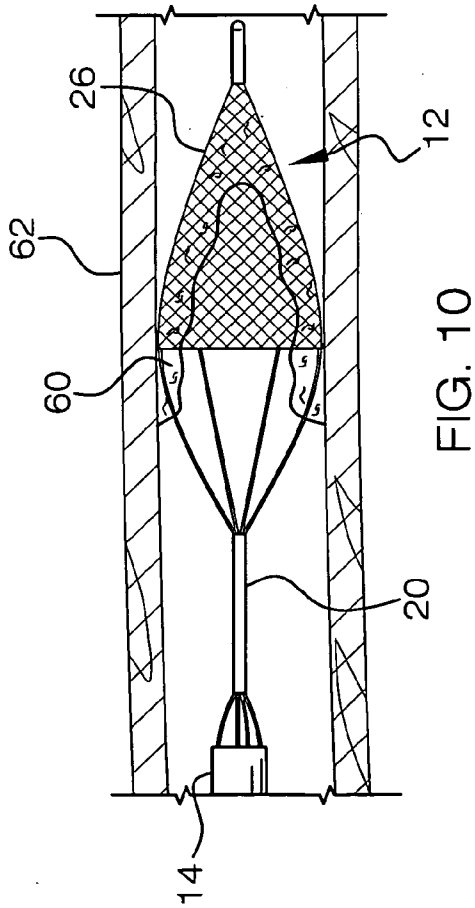


FIG. 10

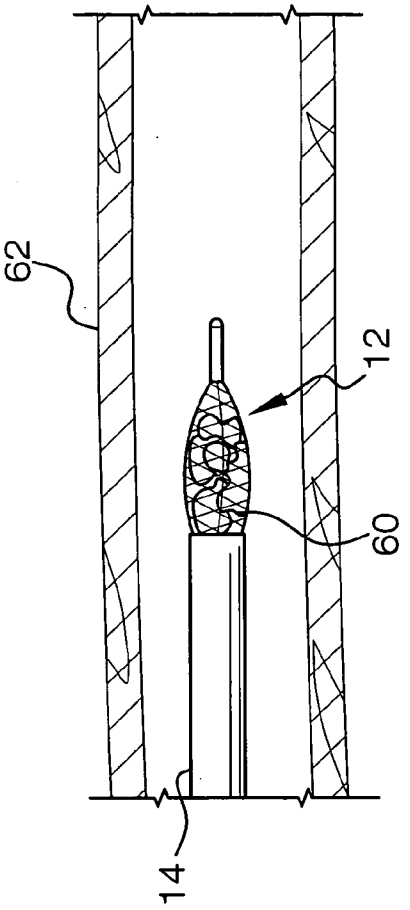


FIG. 11

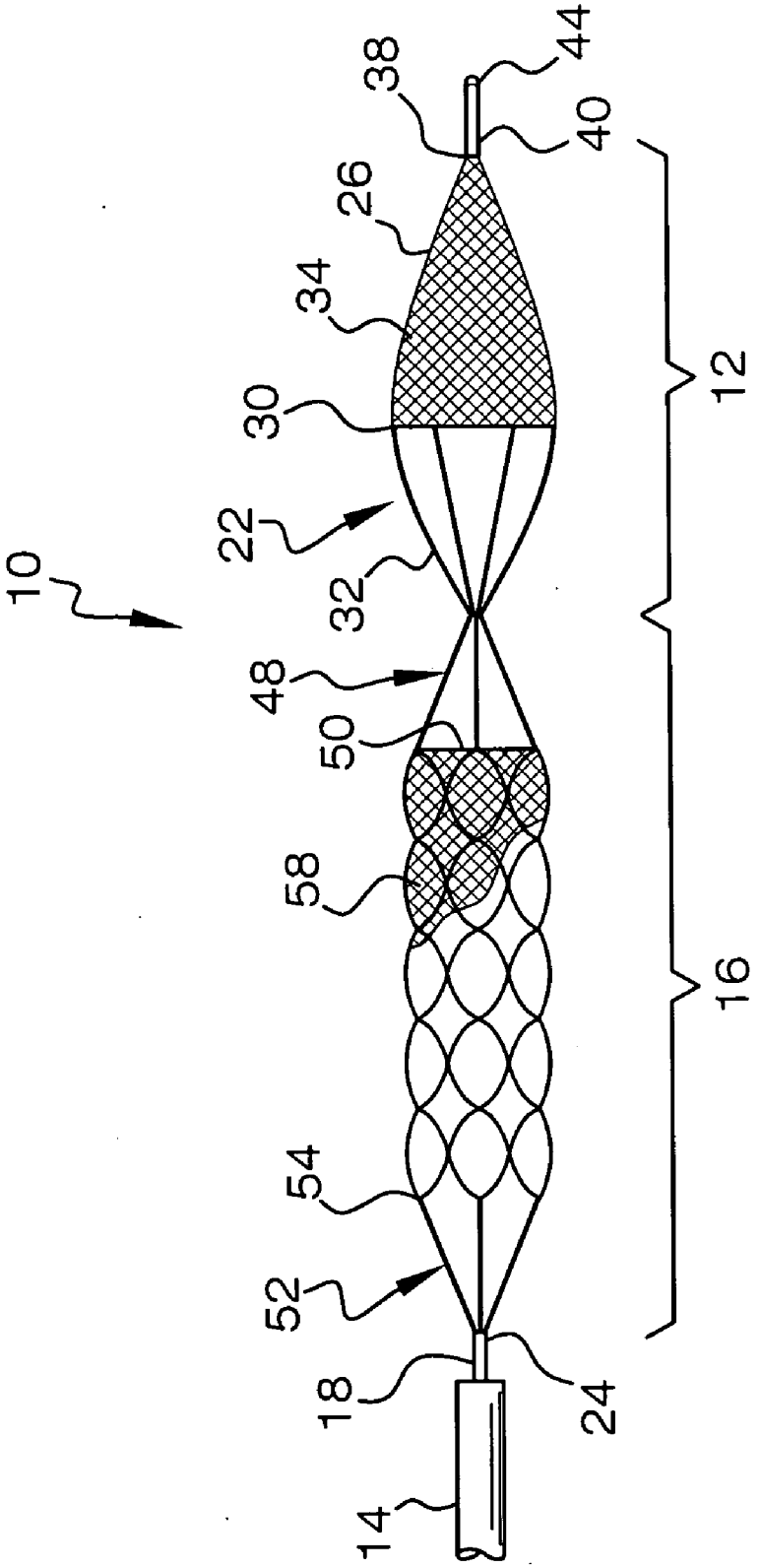


FIG. 12

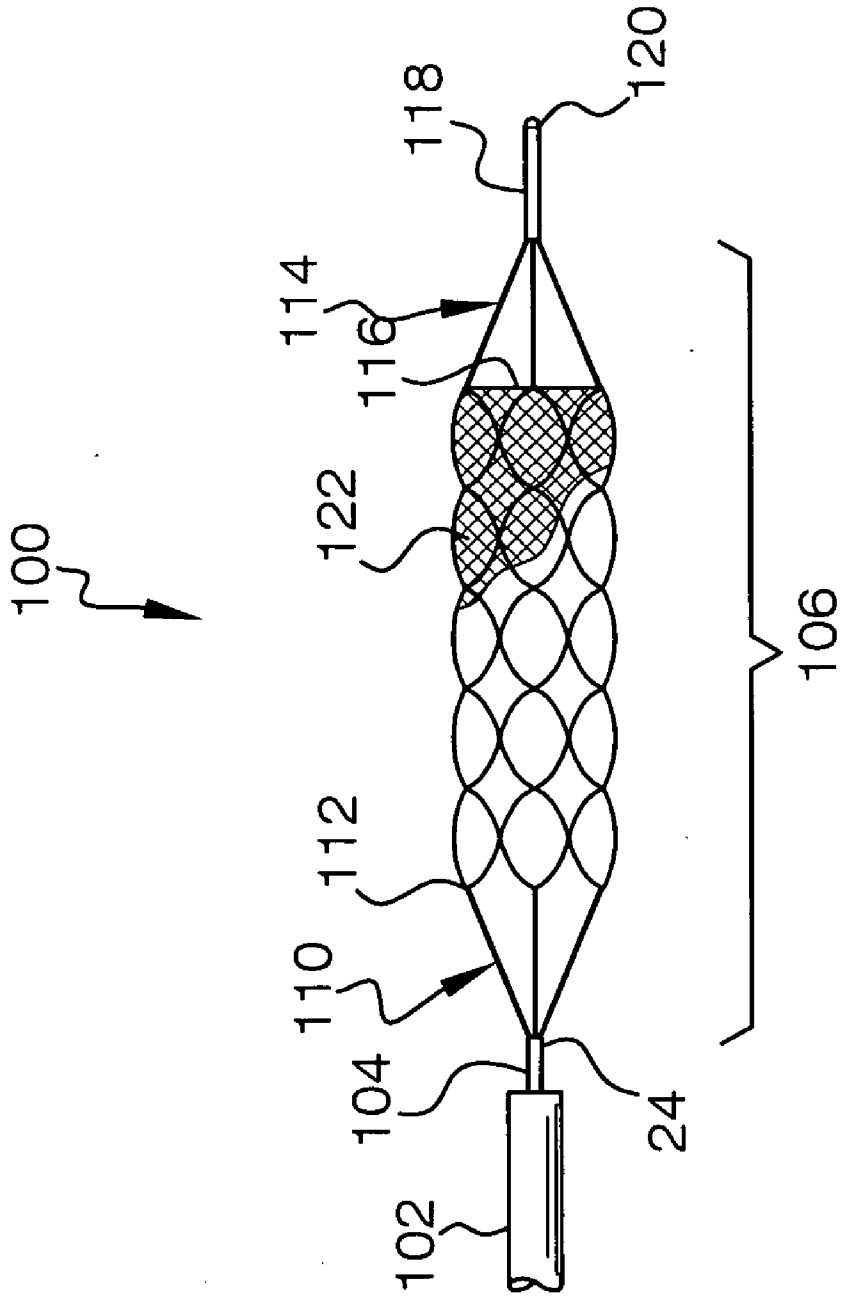


FIG. 13

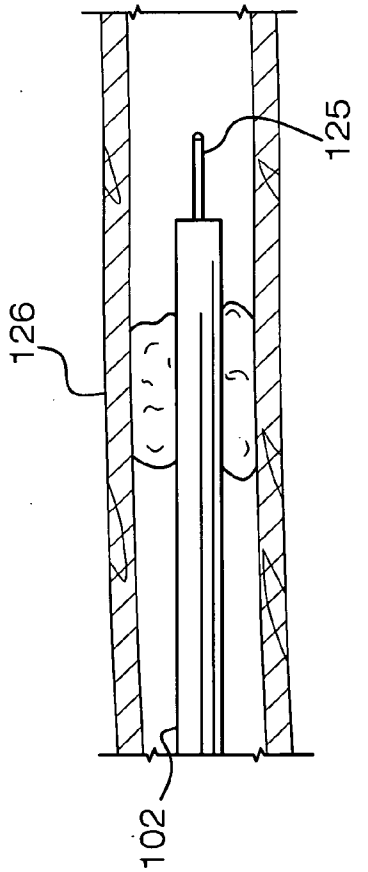


FIG. 14

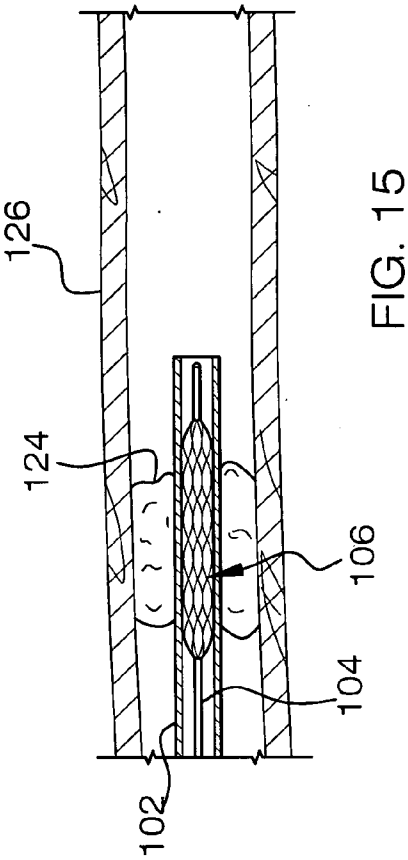


FIG. 15

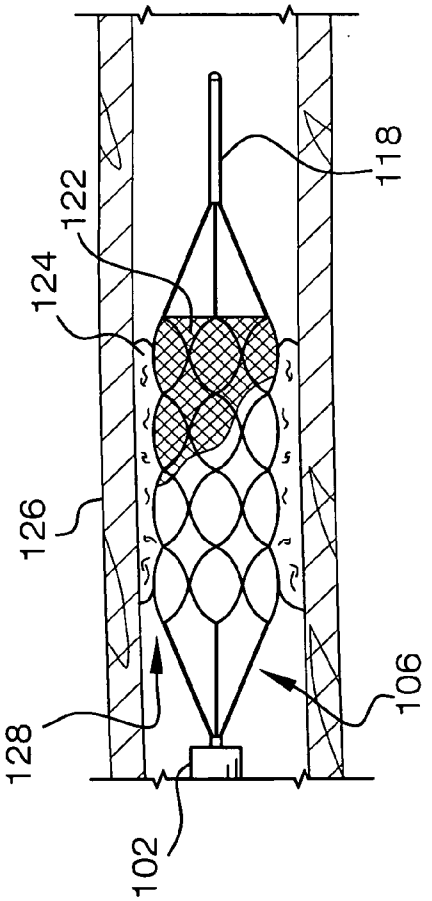


FIG. 16

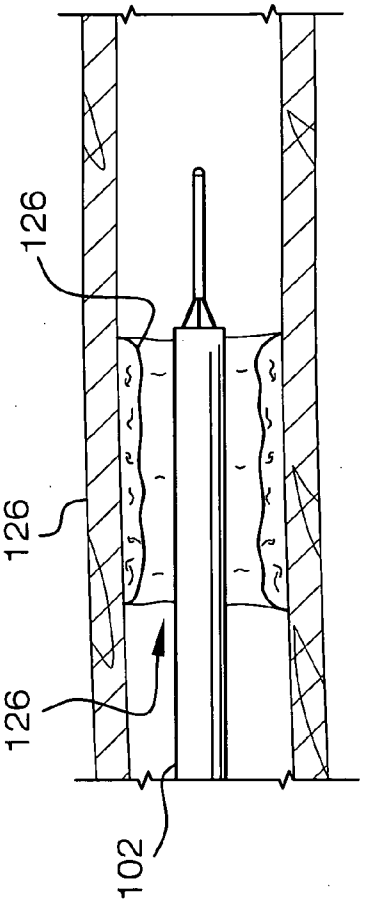


FIG. 17

MECHANICAL EMBOLECTOMY DEVICE AND METHOD

FILED OF THE INVENTION

[0001] The present invention relates generally to embolectomy, and more particularly, relating to a mechanical embolectomy device including a clot expander and a clot particle retriever, and method of using the same.

BACKGROUND OF THE INVENTION

[0002] There are currently in excess of 700,000 new or recurrent strokes every year in the United States. It is the third leading cause of death in the United States after coronary artery disease and cancer. Approximately 40% (>250,000) of strokes are due to large vessel occlusion, potentially requiring a device for treatment.

[0003] Treatment must begin with an evaluation of the patient. Diagnostic neuroimaging is used to obtain noninvasive real-time information about the patient. The goal of therapy is to restore perfusion to the ischemic but potentially salvageable brain tissue rather than to the irreversibly damaged brain tissue, since re-establishing blood flow to such damaged tissue can cause complications such as hemorrhage. Determining the cause and location of the blockage is critical to planning the treatment approach. The most common cause of ischemic stroke is acute embolic occlusion. Most patients with acute ischemic stroke have thromboembolic material occluding large cerebral vessels and hence disruption of cerebral blood flow. Removal of the arterial occlusion in a timely manner can provide a substantial reduction in the size and severity of the cerebral infarction, and improvement in the level of disability among survivors. Treatment varies depending on whether the lesion is proximal or distal, whether there is underlying atherosclerotic stenosis at the occlusion site, and whether the proximal extracranial vessel is opened or closed. Where there are proximal arterial occlusions, the physician may attempt clot retrieval, supplemented by direct catheter-directed thrombolysis. Severe stenosis proximal to the occlusion will usually require treatment of the stenosois before or immediately after restoring intracranial flow.

[0004] A current treatment for acute ischemic stroke is intravenous thrombolysis using tissue-type plasminogen activator (TPA). TPA is a naturally occurring enzyme that activates plasminogen into active plasmin, which dissolves fibrin. The dissolution of fibrin in a clot causes thrombolysis. This treatment is suitable for smaller clots, but has limited utility for patients with large clots, such as are often present in acute occlusions of the internal carotid artery (ICA), proximal middle cerebral artery (MCA), and basilar artery (BA). Also, TPA therapy has significant time constraints, and is generally effective only if given within 3-6 hours of stroke symptom onset. Contraindications to TPA and these time constraints led to mechanical embolectomy.

[0005] Mechanical removal of the thrombus is the goal of mechanical embolectomy. Lytic therapy is necessary for non-accessible locations. Mechanical embolectomy is the process by which a mechanical device is inserted into the body, moved through the affected body canal to the site of the occlusion, and then used to mechanically remove the occlusion from the canal to restore blood flow. One such device is the Mechanical Embolus Removal in Cerebral Ischemia (Merci) retrieval device (Concentric Medical, Mountain View, Calif.), which is currently available for routine clinical use in acute ischemic stroke within 9 hours of onset. This device is a flexible and tapered nickel titanium wire with a helically shaped distal tip that can be deployed intra-arterially to entrap and retrieve large vessel intracerebral clots. Other devices are in various stages of development.

SUMMARY OF THE INVENTION

[0006] In general, in one aspect, an embolectomy device is provided. The embolectomy device includes an elongated shaft positionable in and movable within a catheter. The elongated shaft having a distal end portion. An intermediate elongated shaft positionable in an movable with the catheter. The intermediate elongated shaft having proximal and distal ends. An expander portion having proximal and distal ends. The expander portion having a first plurality of legs connecting the proximal end of the expander portion to the distal end portion of the elongated shaft and a second plurality of legs connecting the distal end of the expander portion to the proximal end of the intermediate elongated shaft. A retrieval portion having a plurality of legs having proximal and distal portions. The proximal portion being attached to the distal end of the intermediate elongated shaft at the proximal portion of the of plurality of legs of the retrieval portion. The plurality of legs of the retrieval portion being movable laterally outward from a long axis of embolectomy device when the retrieval portion has been moved out of the catheter. The expander portion being biased to expand laterally outward from the long axis of the embolectomy device when the expander portion has been moved out of the catheter to engage a clot.

[0007] An atraumatic distal portion can extend distally from the distal end portion of the plurality of legs of the of retrieval portion. A retrieval net can be fixed to the retrieval portion. The net can be constructed from a polymeric material. The expander portion can be at least partially covered by a net. The net can comprises a biocompatible or non-thrombegenic material. The embolectomy device can further include the catheter.

[0008] In general, in another aspect, an embolectomy device is provided. The embolectomy device includes an elongated shaft positionable in and movable within a catheter. The elongated shaft having a distal end portion. An intermediate elongated shaft positionable in an movable with the catheter. The intermediate elongated shaft having proximal and distal ends. An expander portion having proximal and distal ends, and having a first plurality of legs connecting the proximal end of the expander portion to the distal end portion of the elongated shaft and a second plurality of legs connecting the distal end of the expander portion to the proximal end of the intermediate elongated shaft. A retrieval portion having a plurality of legs having proximal and distal ends and a mid-portion between the proximal and distal ends, and the proximal end being attached to the distal end of the intermediate elongated shaft at the proximal end of the of plurality of legs of the retrieval portion. The mid-portion of the legs being movable laterally outward from a long axis of the embolectomy device when the retrieval portion has been moved out of the catheter. The expander portion being biased to expand laterally outward from the long axis of the embolectomy device when the expander portion has been moved out of the catheter to engage a clot.

[0009] A retrieval net can be fixed to the plurality of legs of the retrieval portion between the mid-portion and the distal end thereof. The plurality of legs of the retrieval portion can

be spring arms. The spring arms can comprise a bend at the mid-portion defining proximal and distal portions, the bend biasing the spring arms to a lateral outward position. An atraumatic distal portion can extend distally from the distal end portion of the plurality of legs of the of retrieval portion. The expander portion can be at least partially covered by a net. The net can comprises a biocompatible or non-thrombegenic material. The embolectomy device can further include the catheter. The spring arms can be integral with the intermediate elongated shaft. The spring arms can be attached to the intermediate elongated shaft.

[0010] In general, in another aspect, an embolectomy device is provided. The embolectomy device includes an elongated shaft positionable in and movable within a catheter. The elongated shaft having a distal end portion. An expander portion having proximal and distal ends. The expander portion having a first plurality of legs connecting the proximal end of the expander portion to the distal end portion of the elongated shaft and a second plurality of legs connecting the distal end of the expander portion to the proximal end of the intermediate elongated shaft. The expander portion being biased to expand laterally outward from the long axis of the embolectomy device when the expander portion has been moved out of the catheter to engage a clot.

[0011] An atraumatic distal portion can extend distally from the distal end of the expander portion. The expander portion can be at least partially covered by a net. The net can comprises a biocompatible or non-thrombegenic material. The embolectomy device can further include the catheter.

[0012] In general, in another aspect, a method of performing an embolectomy is provided. The method includes the steps of providing an embolectomy device comprising an elongated shaft positionable in and movable within a catheter, the elongated shaft having a distal end portion, an intermediate elongated shaft positionable in an movable with the catheter, the intermediate elongated shaft having proximal and distal ends, an expander portion having proximal and distal ends, the expander portion having a first plurality of legs connecting the proximal end of the expander portion to the distal end portion of the elongated shaft and a second plurality of legs connecting the distal end of the expander portion to the proximal end of the intermediate elongated shaft, a retrieval portion having a plurality of legs having proximal and distal portions, the proximal portion being attached to the distal end of the intermediate elongated shaft at the proximal portion of the of plurality of legs of the retrieval portion, the plurality of legs of the retrieval portion being movable laterally outward from a long axis of the elongated shaft when the retrieval portion has been moved out of the catheter, the expander portion being biased to expand laterally outward from the long axis of the embolectomy device when the expander portion has been moved out of the catheter to engage an occlusion, and a retrieval net fixed to the retrieval portion. The embolectomy device is manipulated within a catheter to position the expander portion across an occlusion in a body canal. The expander portion is expanded to move the occlusion toward the body canal, thereby creating a lumen. The expander portion is retracted. The retrieval portion is moved proximally so as to engage the occlusion with the retrieval net. The catheter and embolectomy device are removed from the body canal as one with portions of the occlusion contained by the catheter and retrieval portion of the embolectomy device.

[0013] In general, in another aspect, a method of performing an embolectomy is provided. The method includes the steps of providing an embolectomy device including an elongated shaft positionable in and movable within a catheter, the elongated shaft having a distal end portion, an expander portion having proximal and distal ends, the expander portion having a first plurality of legs connecting the proximal end of the expander portion to the distal end portion of the elongated shaft and a second plurality of legs connecting the distal end of the expander portion to the proximal end of the intermediate elongated shaft, the expander portion being biased to expand laterally outward from the long axis of the embolectomy device when the expander portion has been moved out of the catheter to engage an occlusion. The embolectomy device is manipulated within a catheter to position the expander portion across an occlusion in a body canal. The expander portion is expanded to move the occlusion toward the body canal, thereby creating a lumen. The expander portion is retracted, and the catheter and embolectomy device are removed from the body canal leaving the lumen open.

[0014] There has thus been outlined, rather broadly, the more important features of the invention in order that the detailed description thereof that follows may be better understood and in order that the present contribution to the art may be better appreciated.

[0015] Numerous objects, features and advantages of the present invention will be readily apparent to those of ordinary skill in the art upon a reading of the following detailed description of presently preferred, but nonetheless illustrative, embodiments of the present invention when taken in conjunction with the accompanying drawings. The invention is capable of other embodiments and of being practiced and carried out in various ways. Also, it is to be understood that the phraseology and terminology employed herein are for the purpose of descriptions and should not be regarded as limiting.

[0016] As such, those skilled in the art will appreciate that the conception, upon which this disclosure is based, may readily be utilized as a basis for the designing of other structures, methods and systems for carrying out the several purposes of the present invention. It is important, therefore, that the claims be regarded as including such equivalent constructions insofar as they do not depart from the spirit and scope of the present invention.

[0017] For a better understanding of the invention, its operating advantages and the specific objects attained by its uses, reference should be had to the accompanying drawings and descriptive matter in which there is illustrated preferred embodiments of the invention.

BRIEF DESCRIPTION OF THE DRAWINGS

[0018] The accompanying drawings, which are included to provide further understanding of the invention and are incorporated in and constitute a part of this specification, illustrate preferred embodiments of the invention and together with the description serve to explain the principles of the invention, in which:

[0019] FIG. **1** is a side elevation of an embolectomy device in accordance with the principles of the present invention shown fully extended from the microcatheter;

[0020] FIGS. **2-5** are side elevation views of the embolectomy device in accordance with the principles of the present invention shown partially extended from the microcatheter in various stages;

[0021] FIGS. **6-11** are side elevation views of the embolectomy device in accordance with the principles of the present invention shown at various stages of operation removing a clot from a body canal;

[0022] FIG. **12** is a side elevation of an alternative embodiment;

[0023] FIG. **13** is a side elevation of an alternative embodiment; and

[0024] FIGS. **14-17** are side elevation views of the embolectomy device of FIG. **13** at various stages of operation creating a lumen through in a clot in a body canal

DETAILED DESCRIPTION OF THE INVENTION

[0025] There is shown in FIGS. **1-5** an embolectomy device **10** according to the invention. In FIG. **1**, the embolectomy device **10** is shown fully extended. In FIGS. **2-5**, the embolectomy device **10** is shown partially extended in various stages. The embolectomy device **10** is positionable in and movable within a catheter **14**, such as a microcatheter. The embolectomy device **10** includes an elongated shaft such as proximal wire **18** extending through an opening in the microcatheter **14**, an expander portion **16**, and a retrieval portion **12**. The proximal wire **18** can have a proximal end (not shown) and distal end **24**. The expander portion **16** can be provided at the distal end **24** of the proximal wire **18**. The retrieval portion **12** can be provided distally at a spaced distance from the expander portion **16**, and can be connected to the expander portion by an intermediate elongated shaft or intermediate connecting wire **20**.

[0026] The retrieval portion **12** may be formed from or attached to the intermediate connecting wire **20**. The retrieval portion **12** can have a plurality of legs such as spring arms **22** that are connected to the intermediate connecting wire **20**. The spring arms **22** are disposed about a long axis A of the embolectomy device **10**. The spring arms **22** are biased or otherwise moveable to extend partially outwardly (FIG. **3**) when not constrained entirely by the microcatheter **14**. When unconstrained by the microcatheter **14** (FIG. **4**) the spring arms **22** can extend laterally outward a maximum distance. Movement of the spring arms **22** relative to the microcatheter **14** can thereby be used to control the lateral extension of the spring arms **22** within a range of possible distances between full extension and full retraction.

[0027] A retrieval net **26** can be provided on the spring arms **22** to assist in engaging and removing a clot or other obstruction from a body canal. The net **26** can be constructed of a flexible, thin-walled material such that when the spring arms **22** are positioned within the microcatheter **14**, the net can also be contained within the microcatheter **14**. The net **26** can also move freely into and out of the microcatheter **14** with the retrieval portion **12**. The net **26** can be constructed from a porous or a substantially non-porous material, such as a flexible plastic net or solid sheet material, and/or a biocompatible or non-thrombogenic polymer. The net **26** can be formed from a polymeric material that is adhered or otherwise securely fixed to the spring arms

[0028] The precise arrangement and construction of the spring arms **22** can be varied. In the embodiment shown, the spring arms **22** are elongated and substantially radially disposed about the long axis A of the embolectomy device **10**. The spring arms **22** can be formed separately and attached to the intermediate guide wire **20**, or the spring arms **22** can be integral with the intermediate guide wire **20** and formed by suitable techniques, such as, but not limited to computer-controlled laser cutting, plastic injection molding, or casting. The spring arms **22** can have a mid-portion **30**, which can have a bend, crimp, curve, or other biasing or moving feature or structure which causes the legs/spring arms **22** to extend laterally outward relative to the long axis A of the embolectomy device **10**. In one embodiment, the spring arms **22** are at least partially made of an elastic material, such as plastic or metal. The mid-portion **30** defines proximal portions **32** and distal portions **34** of the spring arms **22**. The retrieval portion **12** can be attached to a distal end **28** of the intermediate connecting wire **20** at the proximal portion **32** of the spring legs **22**. When the proximal portions **32** are positioned within the microcatheter **14**, the proximal portions **32** are retained in a laterally inward position by the inside wall of the microcatheter (FIG. **2**). As the embolectomy device **10** is extended from the microcatheter **14**, the spring arms **22** are permitted under the influence of the biasing to extend laterally outward (FIG. **3**). As the embolectomy device **10** is moved further out of the microcatheter **14**, the spring arms **22** are moved by the biasing completely out of the microcatheter **14** and extend a maximum lateral distance from the long axis A of the embolectomy device **10** (FIG. **4**). The distal portions **34** extend from a lateral maximum distance at the bend **30** to a lateral minimum distance at the distal end **38** of the spring arms **22**. The lateral outward extension of the legs/spring arms **22** can thereby be controlled by the distance which the proximal portions **32** are moved out of the microcatheter **14**.

[0029] The net **26** is joined to the distal portions **34** of the spring arms **22**, such that when the spring arms **22** are laterally extended, the net **26** is opened to that in one embodiment is a substantially conical configuration and retained in that position by the spring arms **22**, as shown in FIG. **4**. In this position, the net **26** can engage, capture and retain a clot or other obstruction during an embolectomy. The net **26** also retains debris which otherwise might be left in the body canal. An atraumatic distal portion **40** can be provided at the distal end of the embolectomy device **10** for preventing the embolectomy device from penetrating or piercing a body canal as it is moved therethrough. The distal portion **40** can be part of the intermediate connecting wire **20** or can be a separate structure to which the spring arms **22** are affixed. The distal portion **40** can be flexible and non-rigid. The distal portion **40** can include a blunt atraumatic tip **44**.

[0030] The expander portion **16** may be formed from or attached to the proximal wire **18**. The expander portion **16** is disposed about the long axis A of the embolectomy device **10**, and may be biased or otherwise moveable to extend outwardly when not constrained by the microcatheter **14**. The expander portion **16** may have a plurality of legs **48** that connect a distal end **50** of the expander portion to a proximal end **36** of the intermediate connecting wire **20**, and a plurality of legs **52** that connect a proximal end **54** of the expander portion to the distal end **24** of the proximal wire **18**. Legs **48** and **52** may be spring arms, and biased or otherwise moveable to extend outwardly (FIG. **5**) when not constrained by the microcatheter **14**, similarly to that of spring arms **22**. Additionally, as with spring arms **22**, the construction and arrangement of spring arms **48** and **52** can be varied. In the embodiment shown, the spring arms **48** and **52** are elongated and substantially radially disposed about a long axis A of the embolectomy device **10**. Spring arms **48** and **52** can be formed separately and attached to the proximal wire **18** and intermediate connecting wire **20**, respectively. Spring arms **48** and **52** can be integral with the proximal wire **18** and

intermediate connecting wire **20**, respectively, and can be formed by suitable techniques, such as, but not limited to, computer-controlled laser cutting, plastic injection molding, or casting. In one embodiment, spring arms **48** and **52** are at least partially made of an elastic material, such as plastic or metal.

[0031] A mesh or net **58** can cover a portion or all of the expander portion **16** in order to better engage clot material. The net **58** can be constructed from a porous or a substantially non-porous material, such as a flexible plastic net or solid sheet material, and/or a biocompatible or non-thrombogenic polymer. The net **58** can be integral with the expander portion. Expansion of the expander portion **16** is controlled by suitable means, such as the presence of the microcatheter **14**. When the microcatheter **14** is removed or pulled back from the expander portion **16**, the expander is expanded either by a spring force or a suitable motor.

[0032] The expander portion **16** can be of different designs, but can be a mesh metallic or polymeric device similar to a stent in that it is capable of a first position in which it is tightly compacted laterally, and in another position expands laterally. It is important to understand the expander portion **16** is only stent like, and is not intended to be left in place within a body canal. The expander portion **16** uses this lateral expansion force to spread clot material concentrically outwardly toward the walls of the body canal, opening a lumen through the body canal. In the high energy, compacted state the expander portion **16** is contained within a catheter. When moved out of the catheter, the expander portion **16** assumes an expanded, lower energy state. The expander portion **16** can be completely or partially coated with a polymer, and/or with a therapeutic substance. The expander portion **16** can be porous, non-porous, or partially porous. The expander portion can be formed by suitable techniques, such as, but not limited to, computer-controlled laser cutting, plastic injection molding, or casting.

[0033] Operation of the embolectomy device **10** is shown in FIGS. **6-11**. In FIG. **6**, the microcatheter **14** shown positioned within the body canal **62** through and beyond clot **60** using a steerable microwire **61** and standard interventional radiology techniques. With the microcatheter **14** in position in the body canal **62** and through the clot **60**, the steerable microwire is removed from the microcatheter. A contrasting agent can be injected into the microcatheter **14** to confirm the microcatheter is correctly positioned through the clot **60**. While maintaining the position of microcatheter **14** the embolectomy device **10** is inserted into the microcatheter to position the expander portion **16** across the clot **60** (FIG. **7**). The embolectomy device **10** is extended from the microcatheter **14** by withdrawing the microcatheter **14** proximally while maintaining the positioning of the embolectomy device. As the proximal portions **32** of the retrieval portion **16** emerge from the microcatheter **14** (FIG. **8**), the spring arms **22** begin to extend laterally outward, which extends the mid-portions **30** laterally outward. As the spring arms **22** are moved completely out of the microcatheter **14** (FIG. **9** and **10**), the spring arms **22** extend outward a maximum lateral distance relative to the long axis A of the embolectomy device **10**. Continued withdrawal of the microcatheter **14** exposes the expander portion **16**, which is expanded by either spring force or a suitable motor, pressing the clot **60** against the body canal **62** (FIG. **9**) and creating a lumen. The expander portion **16** can then be collapsed and retracted into the microcatheter **14** by moving the microcatheter distally over the expander portion. With the expander portion **16** contained within the microcatheter **14**, the embolectomy device **10** can be further retracted, by either moving the microcatheter distally over the embolectomy device **10**, moving the embolectomy device proximally into the microcatheter, or a combination of both such that clot **60** will be engaged by the net **26** (FIG. **10**) of the retrieval portion **12** and at least partially pulled into the microcatheter (FIG. **11**). The microcatheter **14** and embolectomy device **10** are then removed from canal **62**, as one unit with the retrieval portion **12** and the microcatheter forming a reservoir for containing the clot or emboli **60**.

[0034] The dimensions and construction of the microcatheter **14**, elongated shaft or guide wire **18**, intermediate guide wire **20**, expander portion **16**, retrieval portion **12**, legs/spring arms **22**, and legs **48** and **52** can vary depending on the size of the canal in which the clot is located, the size and position of the clot, and other factors. The dimensions of the retrieval portion **12** can, for example, be between 0.20 mm to 0.45 mm in diameter when collapsed, and between 0.4 mm to 10 mm when open. In one embodiment the retrieval portion **12** can have a length between 2 mm and 22 mm. The dimensions of the guide wire **18** can in one embodiment be 0.35 mm in diameter, and between 0.20 mm to 0.45 mm in diameter. In another embodiment, the dimensions of the guide wire **18** can be 0.25 mm, and between 0.20 mm to 0.36 mm. The dimensions of the penetrating portion **40** can be 0.25 mm in diameter, or between 0.20 mm and 0.45 mm in diameter. The dimensions of the microcatheter **14** can be an outside diameter (OD) 0.60 mm, and an inside diameter (ID) of 0.43 mm, or with an (OD) between 0.40 mm to 1.37 mm, and an (ID) between 0.25 mm to 0.75 mm. The dimensions of the expander portion **16** can, for example, be between 10 mm and 44 mm in length. The length of the intermediate guide wire **20** can be up to 28 mm. Other dimensions are possible.

[0035] The instruments used to position and manipulate the micro catheter **14** and the guide wire **18** can be standard devices or devices specifically designed for use with the invention. Although the legs have been described as spring arms **22**, the invention is also useful when the legs/spring arms **22** are moved laterally outward by a force other than a spring force, as where the legs are driven laterally outward by a motor of some kind, such as an osmotic pump. In other embodiments, the mid-portion **30** of the legs/spring arms **22** can be at least partially elastic or can comprise a hinge structure to permit bending of the legs/spring arms.

[0036] Other embodiments are possible. There is shown in FIG. **12** an embodiment of the embolectomy device **10** where the intermediate connecting wire **20** is absent, and the retrieval portion **12** is connected directly to the expander portion **16**. Proximal portions **32** of the spring arms **22** can be connected to the legs **48** at the distal end **50** of the expander portion **16**. The remaining aspect can remain as discussed above in the first embodiment shown in FIGS. **1-11**.

[0037] There is shown in FIGS. **13-17** an alternative embodiment of an embolectomy device **100** according to the present invention. In FIG. **13**, the embolectomy device **100** is shown fully extended. In FIGS. **14-17**, the embolectomy device **100** is shown partially extended in various stages during operation in a body canal. The embolectomy device **100** is positionable in and movable within a catheter **102**, such as a microcatheter. The embolectomy device **100** includes an elongated shaft such as proximal wire **104** extending through an opening in the microcatheter **102** and an expander portion **106**. The proximal wire **104** can have a proximal end (not

shown) and distal end **108**. The expander portion **106** can be provided at the distal end **108** of the proximal wire **104**.

[0038] The expander portion **106** may be formed from or attached to the proximal wire **104**. The expander portion **106** is disposed about the long axis A of the embolectomy device **100**, and may be baised or otherwise moveable to extend outwardly when not constrained by the microcatheter **102**. The expander portion **106** may have a plurality of legs **110** at a proximal end **112** of the expander portion, and a plurality of legs **114** at a distal portion end **116** of the expander portion. The proximal end **112** of expander portion **106** can be connected to the distal end **108** of the proximal wire **104**. Legs **110** and **114** may be spring arms, and biased or otherwise moveable to extend outwardly when not constrained by the microcatheter **102**. Additionally, the construction and arrangement of spring arms **110** and **114** can be varied. In the embodiment shown, the spring arms **110** and **114** are elongated and substantially radially disposed about a long axis A of the embolectomy device **100**. Spring arms **110** can be formed separately and attached to the proximal wire **104**. Spring arms **110** can be integral with the proximal wire **104**, and can be formed by suitable techniques, such as, but not limited to, computer-controlled laser cutting, plastic injection molding, or casting.. In one embodiment, spring arms **110** and **114** are at least partially made of an elastic material, such as plastic or metal.

[0039] The expander portion **106** can be of different designs, but can be a mesh metallic or polymeric device similar to a stent in that it is capable of a first position in which it is tightly compacted laterally, and in another position expands laterally. It is important to understand the expander portion **106** is only stent like, and is not intended to be left in place within a body canal. The expander portion **106** uses this lateral expansion force to spread clot material concentrically outwardly toward the walls of the body canal, opening a lumen through the body canal. In the high energy, compacted state the expander portion **106** is contained within a catheter. When moved out of the catheter, the expander portion **106** assumes an expanded, lower energy state. The expander portion **106** can be completely or partially coated with a polymer, and/or with a therapeutic substance. The expander portion **106** can be porous, non-porous, or partially porous. The expander portion can be formed by suitable techniques, such as, but not limited to, computer-controlled laser cutting, plastic injection molding, or casting.

[0040] Expansion of the expander portion **106** is controlled by suitable means, such as the presence of the microcatheter **102**. When the microcatheter **102** is removed or pulled back from the expander portion **106**, the expander portion is expanded either by a spring force or a suitable motor.

[0041] An atraumatic distal portion **118** can be provided at the distal end of the embolectomy device **100** for preventing the embolectomy device from penetrating or piercing a body canal as it is moved therethrough. The distal portion **118** can be part of legs **114** or can be a separate structure to which legs **114** are affixed. The distal portion **118** can be flexible and non-rigid. The distal portion **118** can include a blunt atraumatic tip **120**.

[0042] A mesh or net **122** can cover a portion or all of the expander portion **106** in order to better engage clot material. The net **112** can be constructed from a porous or a substantially non-porous material, such as a flexible plastic net or solid sheet material, and/or a biocompatible or non-thrombogenic polymer. The net **122** can be integral with the expander portion **106**.

[0043] Operation of the embolectomy device **100** is shown in FIGS. **14-17**. In FIG. **14**, the microcatheter **102** is shown positioned within the body canal **126** through and beyond clot **124** using a steerable microwire **125** and standard interventional radiology techniques. With the microcatheter **14** in position in the body canal **126** and through the clot **124**, the steerable microwire is removed from the microcatheter. A contrasting agent can be injected into the microcatheter **102** to confirm the microcatheter is correctly positioned through the clot **124**. While maintaining the position of microcatheter **102** the embolectomy device **100** is inserted into the microcatheter to position the expander portion **106** across the clot **124** (FIG. **15**). The embolectomy device **100** is extended from the microcatheter **102** by withdrawing the microcatheter **102** proximally while maintaining the positioning of the embolectomy device. Continued withdrawal of the microcatheter **102** exposes the expander portion **106**, which is expanded by either spring force or a suitable motor, pressing the clot **124** against the body canal **126** (FIG. **16**) and creating a lumen **128**. The expander portion **106** can then be retracted into the microcatheter **102** by inserting the microcatheter distally over the expander portion **106**. With the expander portion **106** contained within the microcatheter **102**, the embolectomy device **100** can be retracted leaving the lumen **128** and at least partially restoring fluid flow through the body canal **126** (FIG. **17**).

[0044] The dimensions and construction of the microcatheter **102**, elongated shaft or guide wire **104**, expander portion **106**, retrieval portion **12**, and legs **110** and **114** can vary depending on the size of the canal in which the clot is located, the size and position of the clot, and other factors. The dimensions of the guide wire **104** can in one embodiment be 0.35 mm in diameter, and between 0.20 mm to 0.45 mm in diameter. In another embodiment, the dimensions of the guide wire **104** can be 0.25 mm, and between 0.20 mm to 0.36 mm. The dimensions of the penetrating portion **118** can be 0.25 mm in diameter, or between 0.20 mm and 0.45 mm in diameter. The dimensions of the microcatheter **102** can be an outside diameter (OD) 0.60 mm, and an inside diameter (ID) of 0.43 mm, or with an (OD) between 0.40 mm to 1.37 mm, and an (ID) between 0.25 mm to 0.75 mm. The dimensions of the expander portion **106** can, for example, be between 10 mm and 44 mm in length. Other dimensions are possible.

[0045] A number of embodiments of the present invention have been described. Nevertheless, it will be understood that various modifications may be made without departing from the spirit and scope of the invention. Accordingly, other embodiments are within the scope of the following claims.

What is claimed is:

1. An embolectomy device, comprising:

an elongated shaft positionable in and movable within a catheter, said elongated shaft having a distal end portion;

an intermediate elongated shaft positionable in an movable with the catheter; said intermediate elongated shaft having proximal and distal ends;

an expander portion having proximal and distal ends, said expander portion having a first plurality of legs connecting said proximal end of said expander portion to said distal end portion of said elongated shaft and a second

plurality of legs connecting said distal end of said expander portion to said proximal end of said intermediate elongated shaft; and

a retrieval portion having a plurality of legs having proximal and distal portions, said proximal portion being attached to said distal end of said intermediate elongated shaft at said proximal portion of said of plurality of legs of said retrieval portion;

wherein said plurality of legs of said retrieval portion being movable laterally outward from a long axis of the embolectomy device when said retrieval portion has been moved out of the catheter; and

wherein said expander portion being biased to expand laterally outward from said long axis of the embolectomy device when said expander portion has been moved out of the catheter to engage a clot.

2. The embolectomy device of claim **1**, further comprising:

an atraumatic distal portion extending distally from said distal end portion of said plurality of legs of said of retrieval portion.

3. The embolectomy device of claim **1**, further comprising a retrieval net fixed to said retrieval portion.

4. The embolectomy device of claim **3**, wherein said net is constructed from a polymeric material.

5. The embolectomy device of claim **1**, wherein said expander portion is at least partially covered by a net.

6. The embolectomy device of claim **5**, wherein said net comprises a biocompatible or non-thrombegenic material.

7. The embolectomy device of claim **1**, further comprising the catheter.

8. An embolectomy device, comprising:

an elongated shaft positionable in and movable within a catheter, said elongated shaft having a distal end portion;

an intermediate elongated shaft positionable in an movable with the catheter; said intermediate elongated shaft having proximal and distal ends;

an expander portion having proximal and distal ends, said expander portion having a first plurality of legs connecting said proximal end of said expander portion to said distal end portion of said elongated shaft and a second plurality of legs connecting said distal end of said expander portion to said proximal end of said intermediate elongated shaft;

retrieval portion having a plurality of legs having proximal and distal ends and a mid-portion between said proximal and distal ends, said proximal end being attached to said distal end of said intermediate elongated shaft at said proximal end of said of plurality of legs of said retrieval portion;

wherein said mid-portion of said legs being movable laterally outward from a long axis of the embolectomy device when said retrieval portion has been moved out of the catheter; and

wherein said expander portion being biased to expand laterally outward from said long axis of the embolectomy device when said expander portion has been moved out of the catheter to engage a clot.

9. The embolectomy device of claim **8**, further comprising a retrieval net fixed to said plurality of legs of said retrieval portion between said mid-portion and said distal end thereof.

10. The embolectomy device of **8**, wherein said plurality of legs of said retrieval portion are spring arms.

11. The embolectomy device of claim **10**, wherein said spring arms comprise a bend at said mid-portion defining proximal and distal portions, said bend biasing said spring arms to a lateral outward position.

12. The embolectomy device of claim **8**, further comprising:

a atraumatic distal portion extending distally from said distal end portion of said plurality of legs of said of retrieval portion.

13. The embolectomy device of claim **8**, wherein said expander portion is at least partially covered by a net.

14. The embolectomy device of claim **13**, wherein said net comprises a biocompatible or non-thrombegenic material.

15. The embolectomy device of claim **8**, further comprising the catheter.

16. The embolectomy device of claim **11**, wherein said spring arms are integral with said intermediate elongated shaft.

17. The embolectomy device of claim **11**, wherein said spring arms are attached to said intermediate elongated shaft.

18. An embolectomy device, comprising:

an elongated shaft positionable in and movable within a catheter, said elongated shaft having a distal end portion;

an expander portion having proximal and distal ends, said expander portion having a first plurality of legs connecting said proximal end of said expander portion to said distal end portion of said elongated shaft and a second plurality of legs connecting said distal end of said expander portion to said proximal end of said intermediate elongated shaft; and

wherein said expander portion being biased to expand laterally outward from said long axis of the embolectomy device when said expander portion has been moved out of the catheter to engage a clot.

19. The embolectomy device of claim **18**, further comprising:

a atraumatic distal portion extending distally from said distal end of said expander portion.

20. The embolectomy device of claim **18**, wherein said expander portion is at least partially covered by a net.

21. The embolectomy device of claim **20**, wherein said net comprises a biocompatible or non-thrombegenic material.

22. The embolectomy device of claim **18**, further comprising the catheter.

23. A method of performing an embolectomy, comprising the steps of:

providing an embolectomy device comprising an elongated shaft positionable in and movable within a catheter, said elongated shaft having a distal end portion, an intermediate elongated shaft positionable in an movable with the catheter, said intermediate elongated shaft having proximal and distal ends, an expander portion having proximal and distal ends, said expander portion having a first plurality of legs connecting said proximal end of said expander portion to said distal end portion of said elongated shaft and a second plurality of legs connecting said distal end of said expander portion to said proximal end of said intermediate elongated shaft, a retrieval portion having a plurality of legs having proximal and distal portions, said proximal portion being attached to said distal end of said intermediate elongated shaft at said proximal portion of said of plurality of legs of said retrieval portion, said plurality of legs of said retrieval portion being movable laterally outward from a long axis of said elongated shaft when said retrieval portion has been moved out of the catheter, said expander por-

tion being biased to expand laterally outward from said long axis of the embolectomy device when said expander portion has been moved out of the catheter to engage an occlusion, and a retrieval net fixed to said retrieval portion;

manipulating the embolectomy device within a catheter to position the expander portion across an occlusion in a body canal;

expanding the expander portion to move the occlusion toward said body canal, thereby creating a lumen;

retracting the expander portion;

moving the retrieval portion proximally so as to engage said occlusion with the retrieval net; and

removing the catheter and embolectomy device as one from the body canal with portions of the occlusion contained by the catheter and the retrieval portion of the embolectomy device.

24. A method of performing an embolectomy, comprising the steps of:

providing an embolectomy device comprising an elongated shaft positionable in and movable within a catheter, said elongated shaft having a distal end portion, an expander portion having proximal and distal ends, said expander portion having a first plurality of legs connecting said proximal end of said expander portion to said distal end portion of said elongated shaft and a second plurality of legs connecting said distal end of said expander portion to said proximal end of said intermediate elongated shaft, said expander portion being biased to expand laterally outward from said long axis of the embolectomy device when said expander portion has been moved out of the catheter to engage an occlusion;

manipulating the embolectomy device within a catheter to position the expander portion across an occlusion in a body canal;

expanding the expander portion to move the occlusion toward said body canal, thereby creating a lumen;

retracting the expander portion; and

removing the catheter and expander portion from the body canal leaving the lumen open.

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